

### **R E M A R K S**

Entry of this Amendment and reconsideration of this application as amended are respectfully requested.

Claims 1-4, 6-14, 16-22 and 34-54 are pending in this application. Claims 23-32 are cancelled. Claims 5, 15 and 33 are withdrawn from consideration in view of the earlier election of species requirement.

Claims 1, 3-6, 9, 12-14, 17-19, 35, 37, 39, 42, 44, 46-49 and 52 are amended. No new matter is introduced by the changes to the claims. Unless an argument is made below in support of the patentability of each of these claims over the cited prior art, the changes to these claims do not relate to patentability.

#### **Claim Objections**

Claim 19 is amended to clarify that the regulating means set forth in claim 13 comprise the pressure relief valve set forth in claim 19, to thereby overcome the Examiner's objection to the claim.

#### **Claim Rejections-35 U.S.C. 112**

Claim 14 is amended to positively recite an expanded portion and thereby overcome the Examiner's formal rejection of the claim.

#### **Claim Rejections-35 U.S.C. 102/103**

Claims 1-4, 6-13, 16-22 and 34-45 were rejected under 35 U.S.C. 102(b) as being anticipated by Doi et al. (US 4,971,034). Claim 43 was rejected under 35 U.S.C. 103 as being unpatentable over Doi et al. and claims 45-49, 52 and 53 were rejected under 35 U.S.C. 103 as being unpatentable over Doi et al. in view of Jones et al. (US 2003/0120169).

The Examiner's rejections are respectfully traversed in view of changes to independent claims 12, 13 and 35.

Claims 12 and 35 have been amended to clarify the structure of the body of the air introduction device in accordance with the invention. This body defines an interior space and first, second and third lumens communicating with the interior space, has a proximal portion including the first lumen and which is adapted to be inserted into a patient's gastrointestinal tract, a distal portion adapted to mate with an air inflation device via the second lumen to enable air flow through the body into the gastrointestinal tract when the proximal portion is inserted into the patient's gastrointestinal tract and an expanded portion having a larger size than the proximal portion, interposed between the proximal portion and the distal portion and adapted to limit insertion of the proximal portion into the patient's gastrointestinal tract (see the embodiment shown in Figs. 11 and 12). The first and second lumens are arranged on opposite sides of the interior space (in expanded portion 100) such that an air flow generated by the air inflation device when mating with the distal portion 98 flows in a direction from the opening defined by the second lumen 114 into the interior space and then into the patient's gastrointestinal tract through the opening defined by the first lumen (in proximal portion 96) and not outward from the body 94 through the opening defined by the second lumen 114. The third lumen 118 defines an opening communicating with the interior space at a location between the openings defined by the first and second lumens and is arranged such that air being released from the patient's gastrointestinal tract flows in a direction from the interior space through the third lumen. As shown in Figs. 11 and 12, the body 94 is constructed such that the second and third lumens 114, 118 do not overlap and thus the

air that flows in the direction from the opening defined by the second lumen 114 in the direction into the interior space and then into the patient's gastrointestinal tract does not overlap the air flow from the interior space through the third lumen 118.

Further, the air introduction device includes a signal indicator device arranged at least partially within the body and in a fixed position relative to the body, and arranged to generate a signal when a specific air pressure in the patient's gastrointestinal tract is reached (claim 12), or regulating means arranged partially within and in a fixed position relative to the body for regulating air pressure in the patient's gastrointestinal tract by releasing air from the patient's gastrointestinal tract through the third lumen when the air pressure in the patient's gastrointestinal tract exceeds a predetermined pressure.

Claim 13 has also been amended to clarify the structure of the air introduction device in accordance with the invention and now recites that the body defines an interior space and first, second and third lumens communicating therewith and each extending from the interior space in a different direction to provide three different, non-overlapping flow paths to and from the interior space (see Figs. 11 and 12 wherein one flow path is from the opening at the outermost end of lumen 114 to the interior space defined by the expanded portion 100, a second flow path is from the opening at the outermost end of proximal portion 96 to the interior space defined by the expanded portion 100 and the third flow path is from the opening at the outermost end of lumen 118 to the interior space defined by the expanded portion 100). The device includes insertion and sealing means for enabling insertion of a proximal portion 96 of the body including the first lumen into an anus of a person, coupling means for

enabling coupling of the body to an air inflation device via the second lumen such that air is directable from the inflation device in the first flow path from the inflation device into the interior space in the body and then from the interior space in the second flow path out of the body into the person's gastrointestinal tract. The device also includes regulating means arranged partially within the third lumen and to release air from the patient's bowel when the air pressure in the patient's bowel exceeds a predetermined pressure such that the released air flows in the second flow path through into the interior space and then from the interior space in the third flow path out of the body through the third lumen.

Doi et al. and Jones et al. do not disclose, teach or suggest an air introduction device having all of the features of claims 12, 13 and 35.

Doi et al. describes an endoscope system including a mounting cylinder 13 having a nipple 18 to which a gas sending or emitting mechanism 20 is attached via a gas supply pipe 19. A tube 22 extends from the cylinder 13 into the patient's gastrointestinal tract. A valve 37 is associated with the tube 22 to provide a desired pressure in the stomach. Thus, there is a single tube 22 in the endoscope system of Doi et al. through which air is pumped into the stomach and through which air is removed from the stomach (as clearly seen in Fig. 1).

In contrast to the embodiments of the invention set forth in claims 12 and 35, Doi et al. does not include any body having three lumens (a first for inflow of air into an interior space of the body, a second for outflow of air from the interior space into the patient's gastrointestinal tract and a third for outflow of air from the interior space into the ambient atmosphere) and is constructed such that the second and third lumens do not

overlap. Rather, the endoscope system includes only the common tube 22 for air flow from the gas sending and emitting mechanism 20 and for return air flow through valve 37, and thus the air flow path from the gas sending and emitting mechanism 20 passes through the tube 22 to exit the tube into the patient's stomach through the opening at the proximal end, while the air flow path from the patient's stomach also passes through the same tube 22 to the valve 37.

Similarly, in contrast to the embodiment of the invention set forth in claim 13, Doi et al. does not include a body which defines first, second and third lumens communicating with an interior space and each extending from the interior space in a different direction to provide three different, non-overlapping flow paths to and from the interior space.

Jones et al. also does not disclose this feature.

Thus, Doi et al. and Jones et al. cannot teach advantages of the particular formation of the body with three lumens, e.g., the ease of formation and use and described in the specification.

Doi et al. and Jones et al. also do not disclose, teach or suggest features of dependent claims. For example, claims 4, 47 and 49 specify the location of the openings in the three lumens, which features are entirely absent in the endoscope system of Di et al.

In view of the foregoing, it is respectfully submitted that the Examiner's rejections of claims 1-4, 6-14, 16-22 and 33-54 have been overcome and should be removed and that the present application is in condition for allowance.

#### Petition for Extension

Applicant hereby petitions for a two-month extension to extend the time for response to the Office Action dated June 18,

U.S. patent application Ser. No. 10/664,366  
Response to Office Action dated June 18, 2007  
Amendment dated November 19, 2007

2070 for two months from September 18, 2007 to November 19, 2007.  
Payment of the petition fee is being made by credit card upon  
submission of this Amendment. If any additional fees are  
necessary for entry of this Amendment, authorization is hereby  
given to charge any such fees to Deposit Account No. 50-1268.

An early and favorable action on the merits of the invention  
is earnestly solicited.

Respectfully submitted,

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